



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2016-0650; FRL-9972-75]

Isoxaben; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of isoxaben in or on apple, the bushberry subgroup 13-07B, the tree nut group 14-12, and the small vine climbing fruit (except fuzzy kiwifruit) subgroup 13-07F. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective *[insert date of publication in the Federal Register]*.

Objections and requests for hearings must be received on or before *[insert date 60 days after date of publication in the Federal Register]*, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the

SUPPLEMENTARY INFORMATION).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2016-0650, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday,

excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Michael Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: *RDFRNotices@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2016-0650 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2016-0650, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of April 10, 2017 (82 FR 17175) (FRL-9959-61), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 6E8516) by Interregional Research Project No. 4 (IR-4) Project Headquarters, Rutgers, The State University of NJ, 500 College Road East, Suite 201, W, Princeton, NJ 08540. The petition requested that 40 CFR 180.650 be amended by establishing tolerances for residues of the herbicide isoxaben, *N*-[3-(1-ethyl-1-methylpropyl)-5-isoxazolyl]-2, 6-dimethoxybenzamide, in or on the raw agricultural commodities apple at 0.01 parts per million (ppm); the bushberry subgroup 13-07B at 0.01 ppm; the fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F at 0.01 ppm; and the nut, tree, group 14-12 at 0.02 ppm. The petition also requested to remove the tolerances in 40 CFR 180.650 in or on the raw agricultural commodities grape at 0.01 ppm; nut, tree, group 14 at 0.02 ppm; and pistachio at 0.02 ppm. That document referenced a summary of the petition prepared by Dow AgroSciences, the registrant, which is available in the docket,

<http://www.regulations.gov>. Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...."

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for isoxaben including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with isoxaben follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to

human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Isoxaben shows low acute toxicity by all routes. In chronic oral studies, the liver (mouse) and kidney (rat) were target organs, and decreased body weight was observed in the rat, mouse, and dog. There was no indication of neurotoxicity or immunotoxicity. No evidence of increased susceptibility was observed in the rat or rabbit developmental toxicity studies, but was observed in the rat reproductive toxicity study only at the limit dose.

Isoxaben is currently classified as having “suggestive evidence of carcinogenic potential,” based on the presence of liver tumors in male and female mice. Because the tumors were benign and observed at dose levels exceeding the limit dose of 1,000 mg/kg/day and there was low concern for genotoxicity, the cRfD is considered protective of potential carcinogenicity and a quantitative assessment of cancer risk was not conducted.

Specific information on the studies received and the nature of the adverse effects caused by isoxaben as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in the document title “*Isoxaben. Aggregate Human Health Risk Assessment to Support Proposed New Uses on Bushberry Subgroup 13-07B and Apple, Crop Group Conversion (Tree Nut Group 14-12), and Crop Group Expansion (Small Vine Climbing Fruit Except Fuzzy Kiwifruit Subgroup 13-07F)*” on pages 26-31 in docket ID number EPA-HQ-OPP-2016-0650.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides>.

A summary of the toxicological endpoints for isoxaben used for human risk assessment is shown in Table 1 of this unit.

Table 1 Summary of Toxicological Doses and Endpoints for Isoxaben for Use in Human Health Risk Assessment

| Exposure/Scenario | Point of Departure and Uncertainty/Safety Factors | RfD, PAD, LOC for Risk Assessment | Study and Toxicological Effects |
|-------------------|---|-----------------------------------|---------------------------------|
| | | | |

| | | | |
|---|---|---|---|
| Acute dietary (All populations) | An appropriate endpoint for a single exposure was not identified | | |
| Chronic dietary (All populations) | NOAEL= 5.0 mg/kg/day $UF_A = 10x$ $UF_H = 10x$ FQPA SF = 1x | Chronic RfD = 0.05 mg/kg/day cPAD = 0.05 mg/kg/day | Chronic combined toxicity/Carcinogenicity (oral) – rat LOAEL = 50.7 mg/kg/day, based on renal toxicity in males |
| Incidental oral intermediate-term (1 to 6 months) | NOAEL= 200 mg/kg/day $UF_A =$ 10x $UF_H = 10x$ FQPA SF = 1x | LOC for MOE = 100 | Reproductive toxicity (oral) – rat Offspring LOAEL = 1,000 mg/kg/day, based on decreased body weight gain in F ₁ females on day 70, decreased F ₂ pup weights, gestation survival, live pups/litter, and increased incidence of malformations. One-year dietary study (co- critical supporting study) – rat LOAEL = 625 mg/kg/day, based on decreased body weight gain in females during the first six months, with a NOAEL of 62.5 mg/kg/day. |
| Inhalation short- term (1 to 30 days) | NOAEL= 200 mg/kg/day (inhalation toxicity assumed to be equivalent to oral toxicity) $UF_A = 10x$ $UF_H = 10x$ FQPA SF = 1x | LOC for MOE = 100 | Reproductive toxicity (oral) – rat Offspring LOAEL = 1,000 mg/kg/day, based on decreased body weight gain in F ₁ females on day 70, decreased F ₂ pup weights, gestation survival, live pups/litter, and increased incidence of malformations. |

| | | | |
|--|---|-------------------|--|
| Inhalation intermediate-term (1 to 6 months) | NOAEL = 200 mg/kg/day (inhalation toxicity assumed to be equivalent to oral toxicity) $UF_A = 10x$ $UF_H = 10x$ FQPA SF = 1x | LOC for MOE = 100 | Reproductive toxicity (oral) – rat Offspring LOAEL = 1,000 mg/kg/day, based on decreased body weight gain in F ₁ females on day 70, decreased F ₂ pup weights, gestation survival, live pups/litter, and increased incidence of malformations. One-year dietary study (co-critical supporting study) – rat LOAEL = 625 mg/kg/day, based on decreased body weight gain in females during the first six months, with a NOAEL of 62.5 mg/kg/day. |
| Cancer (Oral, dermal, inhalation) | “Suggestive Evidence of Carcinogenic Potential,” based on increased incidence of hepatocellular adenomas in male and female mice. Quantitative assessment of cancer risk using a cancer potency factor is not required. The chronic RfD is protective of potential cancer risk. | | |

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to isoxaben, EPA considered exposure under the petitioned-for tolerances as well as all

existing isoxaben tolerances in 40 CFR 180.650. EPA assessed dietary exposures from isoxaben in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

No such effects were identified in the toxicological studies for isoxaben; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used 2003-2008 food consumption data from the US Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). As to residue levels in food, EPA assumed tolerance-level residues and 100 percent crop treated (PCT).

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that a nonlinear RfD approach is appropriate for assessing cancer risk to isoxaben. Cancer risk was assessed using the same exposure estimates as discussed in Unit III.C.1.ii.

iv. *Anticipated residue and PCT information.* EPA did not use anticipated residue or PCT information in the dietary assessment for isoxaben. Tolerance-level residues and 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* The Agency used screening-level water exposure models in the dietary exposure analysis and risk assessment for isoxaben in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of isoxaben. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at

<http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide>.

Based on the Surface Water Concentration Calculator (SWCC v1.106) and Pesticide Root Zone Model Ground Water (PRZM GW), the estimated drinking water concentrations (EDWCs) of isoxaben for chronic exposures are estimated to be 43.6 parts per billion (ppb) for surface water and 909 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For the chronic dietary risk assessment, the water concentration value of 909 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Isoxaben is currently registered for the following uses that could result in residential exposures: residential turf. EPA assessed residential exposure using the following assumptions: isoxaben residential uses constitute short- and intermediate-term exposure scenarios. For residential handlers, since a dermal endpoint was not selected, the only route of exposure quantitatively assessed for adult handlers is through inhalation. For post-application exposures, only intermediate-term incidental oral exposures for children were assessed due to the persistence of isoxaben residues in soil. Neither a short-term dermal nor short-term incidental oral endpoint was selected for children. Although there is potential for post-application inhalation exposure of both adults and children, the estimated exposure is anticipated to be negligible; therefore, a quantitative post-application inhalation assessment was not required.

For the purpose of performing an aggregate assessment, the Agency selected only the most conservative, or worst-case, residential adult and child scenarios to be included in the aggregate, based on the lowest overall MOE (highest exposure estimates). For adults, handler inhalation exposure resulting from the application of a granular formulation of isoxaben to residential lawns via push-type spreader has been used to estimate adult aggregate exposure. (The inhalation exposure was added to background exposure from food and water, and compared to the short-term inhalation POD.) Post-application risks for adults in residential settings were not assessed due to the lack of a dermal endpoint.

For children, an intermediate-term aggregate assessment was conducted by adding the incidental soil ingestion exposure, and average food and water exposure (chronic dietary exposure). The incidental oral residential exposure value selected for the aggregate analysis is based on children ingesting soil particles containing pesticide residues while playing on treated turf. Due to the persistence of isoxaben in the soil, the Agency used a conservative approach by using the maximum seasonal application rate for estimating soil ingestion by children rather than the standard maximum single application rate. This scenario resulted in the highest calculated exposure levels; therefore, it is protective for all other oral post-application exposure and risk for children in residential settings.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at <http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide>.

4. *Cumulative effects from substances with a common mechanism of toxicity.*

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.”

EPA has not found isoxaben to share a common mechanism of toxicity with any other substances, and isoxaben does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that isoxaben does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides>.

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* No evidence of increased susceptibility was observed in the rat or rabbit developmental toxicity studies, but was observed in the rat reproductive toxicity study only at the limit dose.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for isoxaben is adequately complete to allow the Agency to assess the toxicological profile of isoxaben.

ii. There is no indication that isoxaben is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. No evidence of increased susceptibility was observed in the rat or rabbit developmental toxicity studies, but was observed in the rat reproductive toxicity study only at the limit dose; however, this risk assessment is protective of the susceptibility observed at the limit dose in the reproductive toxicity study.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to isoxaben in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by isoxaben.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, isoxaben is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to isoxaben from food and water will utilize 98% of the cPAD for all infants less than 1-year old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of isoxaben is not expected.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Isoxaben is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to isoxaben.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in an aggregate MOE of 6,700 for females 13-49 years old. Because EPA's level of concern for isoxaben is a MOE of 100 or below, this MOE is not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Isoxaben is currently registered for uses that could result in intermediate-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with intermediate-term residential exposures to isoxaben.

Using the exposure assumptions described in this unit for intermediate-term exposures, EPA has concluded that the combined intermediate-term food, water, and residential exposures result in an aggregate MOE of 7,200 for children 1-2 years old. Because EPA's level of concern for isoxaben is a MOE of 100 or below, this MOE is not of concern.

5. *Aggregate cancer risk for U.S. population.* Based on the discussion in Unit III.A., EPA considers the chronic aggregate risk assessment to be protective of any aggregate cancer risk. As there is no chronic risk of concern, EPA does not expect any cancer risk to the U.S. population from aggregate exposure to isoxaben.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children, from aggregate exposure to isoxaben residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

An adequate residue analytical method (RAM) utilizing liquid chromatography with tandem mass spectrometric detection (LC/MS/MS), GRM 02.26.S.1 (a revision of GRM 02.26), is available for enforcement of isoxaben residues in crop commodities.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established any MRLs for isoxaben.

C. Response to Comments

Seven comments were received in response to the notice of filing. All of the comments were general in nature, not specific to the chemical isoxaben. They included

statements such as “I am not in favor of relaxing requirements on pesticides,” “I am opposed to this proposal,” and “My body doesn’t live well on pesticides.”

The Agency recognizes that some individuals believe that pesticides should be banned on agricultural crops; however, the existing legal framework provided by section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA) states that tolerances may be set when persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by that statute. These citizens’ comments appear to be directed at the underlying statute and not EPA’s implementation of it; the citizens have made no contention that EPA has acted in violation of the statutory framework nor have they provided any specific information or allegation that would support a finding that these tolerances are unsafe.

V. Conclusion

Therefore, tolerances are established for residues of isoxaben including its metabolites and degradates, in or on apple at 0.01 ppm; the bushberry subgroup 13-07B at 0.01 ppm; the fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F at 0.01 ppm; and the nut, tree, group 14-12 at 0.02 ppm. In addition, the following existing tolerances are removed since they are superseded by the new tolerances: grape, nut, tree, group 14; and pistachio.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action

has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001); Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997); or Executive Order 13771, entitled “Reducing Regulations and Controlling Regulatory Costs” (82 FR 9339, February 3, 2017). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined

that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: January 19, 2018.

Donna S. Davis,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In § 180.650, revise the table in paragraph (a) to read as follows:

§ 180.650 Isoxaben; tolerances for residues.

(a) * * *

| Commodity | Parts per million |
|--|-------------------|
| Almond, hulls | 0.40 |
| Apple | 0.01 |
| Bushberry subgroup 13-07B | 0.01 |
| Fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F | 0.01 |
| Nut, tree, group 14-12 | 0.02 |

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